



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/720,452

11/24/2003

Scott Gubler

48939-01070

4084

34013 7590 12/23/2008
HOLME ROBERTS & OWEN, LLP
299 SOUTH MAIN
SUITE 1800
SALT LAKE CITY, UT 84111

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/720,452 | Applicant(s) GUBLER ET AL. | |
| | Examiner Renee Claytor | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 9/17/2008 is acknowledged. Applicants argue over the 35 USC 102 and 103 rejections over Hunsicker et al. that Hunsicker teaches spraying the binder onto a fluidized bed of the powder and that the present invention avoids spraying the binder on a fluidized bed of tocopheryl succinate.

In response to the above arguments, it is noted that the claims broadly read on spraying a liquid onto the mixture of the tocopheryl succinate and binder in a granulator. The claims do not specify a particular granulator. There is no indication that a fluidized-bed granulator would be ineffective in the present composition of claim 1. Therefore the rejection is maintained because the claim broadly reads on a granulator of which Hunsicker teaches the use of a granulator.

The rejections are maintained and given below for Applicant's convenience.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 9-32 rejected under 35 U.S.C. 102(b) as being anticipated by Hunsicker et al. (US Patent 6,130,343).

Hunsicker et al. teaches a method for making a tocopherol product which comprises providing an amount of tocopherol succinate and binder (Col. 3, lines 1-5).

Art Unit: 1617

The process involves spray-coating the tocopheryl succinate with a solution containing a binder in a fluidized-bed granulation apparatus (Col. 3, lines 11-20). Water is typically employed as the solvent, though it is taught that organic solvents can also be used in the solution for spray coating (Col. 4, lines 12-16 and 55-58). Example 1 teaches mixing tocopheryl succinate and a binder and spraying a liquid mixture of the binder and water into the mix all within a fluidized-bed granulation apparatus (Col. 7, lines 17-38). The mixture of the water and the binder is about 10% by weight, which falls within the ranges taught in claims 13-14 (Example 1). The temperature in the granulator has a maximum setting of 30°C, which falls within the ranges taught in claims 15-16 (Example 1). Hunsicker et al. teaches that the product should be maintained in a fluidized state until the desired degree of evaporation has been obtained (Col. 5, lines 50-55). It is also taught that the moisture of the product in the bed is tested periodically (Example 1). The tocopheryl succinate granules can be used in the manufacture of tablets (Col. 6, lines 25-46).

Furthermore, it has been held that merely changing the order of steps in a multi-step process is not a patentable modification absent a showing of unexpected results.

Ex parte Rubin 128 USPQ 440 (POBA 1959.)

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 and 42-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Hunsicker et al. (US Patent 6,130,343) as applied to claims 1-5 and 9-32 above and further in view of Anderson et al. (US Patent 2,791,584).

Hunsicker et al. teach a method for making a tocopherol product as discussed above.

Hunsicker et al. do not specifically teach heating the water to a temperature above 80 degrees C before spraying the liquid onto the mixture.

Anderson et al. teach a method of heating a binder, in particular a methyl cellulose, in an effort to dissolve the methyl cellulose and have a more uniform distribution of water throughout the mass of methyl cellulose (Col. 2, lines 19-40). It is taught that the treatment is most preferably carried out at a temperature above 70°C. See in particular Example 1 in which methyl cellulose was mixed with water at 80°C.

Accordingly, it would be obvious to a person having ordinary skill in the art at the time of the invention to heat the water of the Hunsicker et al. invention to a temperature above 80 degrees C as taught by Anderson et al. One would be motivated to do this in an effort to completely dissolve the binder in the water in an effort to spray over the tocopheryl succinate.

It is noted that the claim limitation in new claim 42 that the mixing of the binder solution with a tocopheryl succinate substance in a high shear granulator is obvious in light of the above rejections. It is noted that both the present invention and the prior art

Art Unit: 1617

teach granulation and the result is a tocopherol product. Absent a showing of unexpected results that the tocopherol product is somehow different with a high shear granulator compared to a fluidized-bed granulator, the present invention is deemed obvious over the prior art.

Conclusion

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617